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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,963	10/31/2003	Kathryn Chung	49321-103	8820

22504 7590 06/27/2007

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EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
06/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,963	CHUNG ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *1-3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/4/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Election/Restrictions

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant's election of Group II claims 4-10 in the reply filed on 2/16/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Caroff et al. (PTO-1449: Treatment of Tardive Dyskinesia With Donepezil A Pilot Study,

October 2001, J. Clinical Psychiatry, 62:10, pp 772-775) as evidenced by applicants own admission (see specification pages 5-6).

Caroff et al. teach, on page 772, that an 8-week open label trial of donepezil in the treatment of tardive dyskinesia (TD) was carried out. Ten patients with TD were treated with donepezil (5 to 10 mg/day) for 6-weeks after a 2-week baseline period. The patients were monitored for changes in their total Abnormal Involuntary Movement Scale (AIMS) scores measured every 2-weeks. The study showed that nine patients receiving donepezil showed a positive improvement with no significant adverse interactions anticipating the "...method for ameliorating hyperkinetic movement disorder comprising administering...a therapeutically effective amount of donepezil..." of claim 4; the "...method...wherein the donepezil is administered in an amount of about 1 to about 50 mg per day" of claim 5; the "...method...wherein the donepezil is administered in an amount of about 2.5 to 25 mg per day" of claim 6; and the "...method...wherein the donepezil is administered in an amount of about 2 to 10 mg per day" of claim 7.

Pages 5-6 of the current specification state:

"In addition to treatment of dystonia with donepezil, the invention also relates to use of donepezil for treatment of other hyperkinetic movement disorders. The term "hyperkinetic movement disorders" refers to conditions such as tremor, chorea, tics, dyskinesia, and dystonia, including dystonic tremor. Hyperkinetic movement disorders can be classified generally into several catogories, including tics, tremors, dyskinesia, and chorea. Tremors can be classified as essential and dystonic, with essential being the more common of the two. Dyskinesias can be idiopathic and tardive."

Thus claims 8-10 are inherently anticipated by Caroff et al. as applicant's have admitted that dystonia, dystonic tremors and dyskinesias (idiopathic and tardive) are hyperkinetic movement disorders and as Caroff et al. clearly demonstrates efficacious treatment of TD, a hyperkinetic movement disorder, with donepezil; treatment of other hyperkinetic disorders such as dystonic tremor are anticipated.

Claims 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Caroff et al. (PTO-1449: Treatment of Tardive Dyskinesia With Donepezil, February 2001, J. Clinical Psychiatry, 62:2).

Caroff et al. teach on page 2 of the article, that treatment for 6 weeks with donepezil (5 to 10 mg/day) appeared to diminish TD by 22%, 74% and 78% in 3 patients with TD anticipating the "...method for ameliorating hyperkinetic movement disorder comprising administering...a therapeutically effective amount of donepezil..." of claim 4; the "...method...wherein the donepezil is administered in an amount of about 1 to about 50 mg per day" of claim 5; the "...method...wherein the donepezil is administered in an amount of about 2.5 to 25 mg per day" of claim 6; and the "...method...wherein the donepezil is administered in an amount of about 2 to 10 mg per day" of claim 7.

Pages 5-6 of the current specification state:

"In addition to treatment of dystonia with donepezil, the invention also relates to use of donepezil for treatment of other hyperkinetic movement disorders. The term

"hyperkinetic movement disorders" refers to conditions such as tremor, chorea, tics, dyskinesia, and dystonia, including dystonic tremor. Hyperkinetic movement disorders can be classified generally into several catogories, including tics, tremors, dyskinesia, and chorea. Tremors can be classified as essential and dystonic, with essential being the more common of the two. Dyskinesias can be idiopathic and tardive."

Thus claims 8-10 are inherently anticipated by Caroff et al. as applicant's have admitted that dystonia, dystonic tremors and dyskinesias (idiopathic and tardive) are hyperkinetic movement disorders and as Caroff et al. clearly demonstrates efficacious treatment of TD, a hyperkinetic movement disorder, with donepezil; treatment of other hyperkinetic disorders such as dystonic tremor are anticipated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER